R68. Agriculture and Food, Plant Industry.

R68-29. Quality Assurance Testing on Cannabis.

R68-29-1. Authority and Purpose.

1) Pursuant to sections 4-41-403(1) and 4-41a-701(3), this rule establishes the standards for cannabis, industrial hemp, cannabis product, and cannabinoid product potency testing and sets limits for water activity, foreign matter, microbiological life, pesticides, residual solvents, heavy metals, and mycotoxins.

R68-29-2. Definitions.

- 1) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including:
 - a) pesticides,
 - b) heavy metals,
 - c) solvents,
 - d) microbiological life,
 - e) toxins, or
 - f) foreign matter.
- 2) "Analyte" means a substance or chemical component that is undergoing analysis.
 - 3) "Batch" means a quantity of:
- a) cannabis extract produced on a particular date and time, following clean up until the next clean up during which $\underline{\text{the same}}$ lots of cannabis are used;
- b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis extract is used; or
- c) cannabis flower from a single strain and growing cycle packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.
 - 4) "Cannabinoid" means any:
- a) naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1), or
- b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.
- 5) "Cannabinoid product" means a product containing material derived from hemp that:
 - a) is processed into a medicinal dosage form; and
- b) contains less than 0.3% tetrahydrocannabinol by dry weight.
 - 6) "Cannabis" means any part of the marijuana plant.
 - 7) "Cannabis cultivation facility" means a person that:
 - a) possesses cannabis;
 - b) grows or intends to grow cannabis; and
- c) sells or intends to sell cannabis to a cannabis cultivation facility or a cannabis processing facility.
 - 8) "Cannabis processing facility" means a person that:

- a) acquires or intends to acquire cannabis from a cannabis production establishment or a holder of an industrial hemp processor license under title 4 chapter 41, Hemp and Cannabidiol Act;
- b) possesses cannabis with the intent to manufacture a cannabis product;
- c) manufactures or intends to manufacture a cannabis product from unprocessed cannabis or cannabis extract; and
- d) sells or intends to sell a cannabis product to a medical cannabis pharmacy or the state central fill medical cannabis pharmacy.
 - 9) "Cannabis product" means a product that:
 - a) is intended for human use; and
 - b) contains cannabis or tetrahydrocannabinol.
 - 10) "CBD" means cannabidiol (CAS 13956-29-1).
 - 11) "CBDA" means cannabidiolic acid, (CAS 1244-58-2).
- 12) "Certificate of analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for which testing was performed.
- 13) "Department" means the Utah Department of Agriculture and Food.
- 14) "Final product" means a reasonably homogenous cannabis product in its final packaged form created using the same standard operating procedures and the same formulation.
 - 15) "Foreign matter" means:
- a) any matter which is present in a cannabis lot that is not a part of the cannabis plant, or
- b) any matter that is present in a cannabis or cannabinoid product that is not listed as an ingredient.
- 16) "Industrial hemp" means a cannabis plant which contains less than 0.3% total THC by dry weight.
- 17) "Hot crude oil" means a cannabinoid extract derived from industrial hemp with greater than 0.3% THC by mass.
 - 18) "Lot" means the quantity of:
- a) flower from a single strain of cannabis and growing cycle produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or
- b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.
 - 19) "Pest" means:
 - a) any insect, rodent, nematode, fungus, weed; or
- b) any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment or that the department declares to be a pest.
 - 20) "Pesticide" means any:

- a) substance or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest or that the commissioner declares to be a pest;
- b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and
- c) any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own used with a pesticide to aid in the application or effect of a pesticide.
- 21) "Sampling technician" means a person tasked with collecting a representative sample of a cannabis lot, cannabis product, hot crude oil, or industrial hemp from a cannabis production establishment who is:
 - a) an employee of the department;
- b) an employee of an independent cannabis laboratory that is licensed by the department to perform sampling; or
- c) a person authorized by the department to perform sampling.
- 22) "Standard operating procedure" (SOP) means a document providing detailed instruction for the performance of a task.
- 23) "THC" means **delta**-9-tetrahydrocannabinoid (CAS 1972-08-3).
- 24) "THCA" means **delta**-9-tetrahydrocannabinolic acid (CAS 23978-85-0).
- 25) "Total CBD" means the sum of the determined amounts of CBD and CBDA.
- 26) "Total THC" means the sum of the determined amounts of THC and THCA.
 - 27) "Unit" means:
 - a) one tablet;
 - b) one capsule;
 - c) 10 ml of concentrated oil or one vape cartridge;
 - d) 10 ml of liquid extract or suspension;
 - e) 0.5 oz of topical preparation;
 - f) one patch or 0.5 oz of transdermal preparation;
 - g) 10 ml of sublingual preparation; or
- h) one gelatinous cube, gelatinous rectangular cuboid, or lozenge in a cube or rectangular cuboid shape; or
- g) each individual portion of an individually packaged product.
- 28) "Water activity" is a dimensionless measure of the water present in a substance that is available to microorganisms; calculated as the partial vapor pressure of water in the substance

divided by the standard state partial vapor pressure of pure water at the same temperature.

R68-29-3. Required Cannabis and Cannabis Product Tests.

- 1) Prior to the transfer of a cannabis lot, a cannabis cultivation facility shall have an independent cannabis laboratory test a representative sample of the lot for potency, water activity, and adulterants, with the exception of solvents.
- 2) A cannabis lot that fails any of the required adulterant testing standards may be remediated by the cannabis cultivation facility or a cannabis processing facility after submitting and gaining approval for a remediation plan from the department.
- 4) Prior to offering a cannabis or cannabis product batch for sale the cannabis processing facility shall have the product tested for potency, water activity, and adulterants.
- 5) A batch of cannabis or cannabis product that fails a required testing standard may be remediated by a cannabis processing facility if:
- a) the cannabis processing facility submits a remediation plan; and
 - b) the remediation plan is approved by the department.
- 6) A remediation plan shall be submitted to the department within 15 days of the receipt of a failed testing result.
- 7) A remediation plan shall be carried out and the cannabis lot or cannabis product batch shall be prepared for resampling within 60 days of department approval of the remediation plan.
- 8) Resampling or retesting of a cannabis lot or batch that fails any of the required testing standards is not allowed until the lot or batch has been remediated.
- 9) A cannabis lot or cannabis product batch that is not or cannot be remediated in the specified time period shall be destroyed.
- 10) A cannabinoid product shall be tested by an independent testing laboratory for microbiological contaminants, heavy metals, pesticides, and residual solvents prior to the product being registered with the department in accordance with Section 4-41-402
- 11) Product tested by the department may be offered for sale without all of the required testing if:
- a) the product packaging discloses the tests that were not performed; and
- b) the disclosure is contained on a sticker provided by the department.
- 12) In the event that tests results cannot be retained in the Inventory Control System, the laboratory shall:
 - a) keep a record of all test results;

- b) issue a certificate of analysis for all required tests; and
- c) retain a copy of the certificate of analysis on the laboratory premises.

R68-29-4. Sampling Cannabis and Cannabis Products.

- _____1) The entity that requests testing of a cannabis lot or cannabis product batch shall make the entirety of the cannabis lot or cannabis batch available to the sampling technician.
- 2) The cannabis lot or cannabis batch being sampled shall be contained in a single location and physically separated from other cannabis lots or cannabis batches.
- 3) The sample shall be collected by a sampling technician who is unaffiliated with the entity that requested testing of the cannabis lot or cannabis product batch unless an exception is granted by the department.
- 4) The owner of the cannabis lot or cannabis product batch and any of their employees shall not assist in the collection of the sample.
- 5) The sampling technician shall collect the representative sample in a manner set forth in a SOP, which is ISO 17025 compliant, maintained by the laboratory that will perform the testing.
- 6) When collecting the representative sample, the sampling technician shall:
- a) use sterile gloves, instruments, and a glass or plastic container to collect the sample;
 - b) place tamper proof tape on the container; and
 - c) appropriately label the sample according to R68-30-6.
- 7) For cannabis lots the minimum representative sample shall be taken according to the following schedule:
- a) 8 subunits weighing at least 0.5 grams each for lots weighing 10 pounds or less;
- b) 16 subunits weighing at least 0.5 grams each for lots weighing 10.01-20 pounds;
- c) 22 subunits weighing at least 0.5 grams each for lots weighing 20.01-30 pounds;
- d) 28 subunits weighing at least 0.5 grams each for lots weighing 30.01-40 pounds;
- e) 32 subunits weighing at least 0.5 grams each for lots weighing 40.01-50 pounds.
- 8) For cannabis products in their final product form the following minimum number of sample units must be taken:
- a) four units for a sample product batch with 5-500 products;
- b) six units for a sample product batch with 501-1000 products;

- c) eight units for a sample product batch with 1,001-5,000 products; and
- d) ten units for a sample product batch with 5,001-10,000 products.
- 9) Additional material may be included in the representative sample if the material is necessary to perform the required testing.

R68-29-5. Moisture Content Testing and Water Activity Standards.

- 1) The moisture content of a sample and related lot of cannabis shall be reported on the COA as a mass over mass percentage.
- 2) A sample and related lot of cannabis fail quality assurance testing if the water activity of the representative sample is found to be greater than 0.65.
- 3) A sample and related cannabis or cannabinoid product batch intended for human consumption fail quality assurance testing if the water activity of the representative sample is greater than 0.65, unless water is a component of the product formulation and is listed as an ingredient.

R68-29-6. Foreign Matter Standards.

- 1) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing if:
- a) the sample contains foreign matter visible to the unaided human eye;
- b) the sample is found to contain microscopic foreign matter estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory; or
- c) foreign matter is found which is suspected to have been intentionally added to the sample to increase its visual appeal or market value.

R68-29-7. Potency Testing.

- 1) A lot or batch of cannabis, cannabis product, cannabinoid product, or hot crude oil shall have their potency determined and listed on a COA as total THC and total CBD.
- 2) A sample and related lot or batch of hemp or cannabinoid product fail quality assurance testing if the total THC is found to be greater than 0.3% of the product mass.

R68-29-8. Microbiological Standards.

1) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing for microbiological contaminants if the results exceed the limits as set forth in Section 1111 of the United States Pharmacopeia.

2) The Department adopts by reference Section 1111 of the United States Pharmacopeia (May 1,2012).

R68-29-9. Pesticide Standards.

- 1) Only pesticides allowed by the department may be used in the production of cannabis, cannabis products, or cannabinoid products.
- 2) If an independent cannabis laboratory identifies a pesticide that is not allowed under R68-29-5(1) and is above the action levels provided in R68-29-5(3) that lot or batch from which the sample was taken has failed quality assurance testing.
- 3) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing for pesticides if the results exceed the limits as set forth on the table below.

Table 1
Pesticide Analytes and Action Levels

Analyte	Chemical Abstract Service (CAS) Registry number	Action Level
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
=	57960-19-7	2
	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
2	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4

Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazon	78587-05-0	1
Imazal	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	143390-89-0	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

- 4) Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).
- 5) Pyrethrins should be measured as the cumulative residues of pyrethrin 1 (CAS 121-21-1), cinerin 1 (CAS 25402-06-6), and jasmolin 1 (CAS 4466-14-2).

R68-29-10. Residual Solvent Standards.

- 1) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fails quality assurance testing for residual solvents if the results exceed the limits provided in the table below unless the solvent is:
 - a) a component of the product formulation,

- b) listed as an ingredient, and
- c) generally considered to be safe for the intended form of use.

Table 2
List of Solvents and Action Levels

Solvent	Chemical Abstract Service (CAS) Registry number	Action level
1,2 Dimethoxyethane	110-71-4	g/g 100
1,4 Dioxane	123-9	380
1-Butanol	71-36-3	5000
	71-36-3	5000
1-Pentanol		
1-Propanol	71-23-8	5000
2-Butanol	78-92-2	5000
[2-Butanol] <u>2-Butanone</u>		5000
2-Ethoxyethanol	110-80-5	160
2-methylbutane	78-78-4	5000
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butane	106-97-8	5000
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
2,2-dimethylbutane	75-83-2	290
2,3-dimethylbutane	79-29-8	290
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
1,4-dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5000
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
n-Hexane	110-54-3	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Methylpropane	75-28-5	5000
2-Methylpentane	107-83-5	290
3-Methylpentane	96-14-0	290
N, N-dimethylacetamide	127-19-5	1090
N, N -dimethylformamide	68-12-2	880

Pentane	109-66-0	5000
Propane	74-98-6	5000
Pyridine	110-86-1	100
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes	1330-20-7	2170

- 2) Xylenes is a combination of the following:
- a) 1,2-dimethylbenzene;
- b) 1,3-dimethylbenzene;
- c) 1,4-dimethylbenzene; and
- d) ethyl benzene.

R68-29-11. Heavy Metal Standards.

A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing for heavy metals if the results exceed the limits provided in the table below.

Table 3
Heavy Metals

Metals	Natural	Health	Products	Acceptable

limits in parts per million

Arsenic <2
Cadmium <0.82
Lead <1.2
Mercury <0.4

R68-29-12. Mycotoxin Standards.

A sample and related lot or batch of cannabis, $\frac{\partial r}{\partial t}$ cannabis product, or cannabinoid product fail quality assurance testing for mycotoxin if the results exceed the limits provided in the table below.

Table 4 Mycotoxin

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Test	Specification
1696	DDECTITCACTOIL

The total of Aflatoxin B1, Aflatoxin B2, Aflatoxin G1,and

Aflatoxin G2 <20 G/kg of substance Ochratoxin A. <20 G/kg of substance

KEY: cannabis testing, quality assurance, cannabis laboratory
Date of Enactment or Last Substantive Amendment:
Authorizing, and Implemented or Interpreted Law: 4-41a-701(3); 4-41-403(1)